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Industry Solution Guide

BONE SCREWS & IMPLANTS MARKING APPLICATION

July 24, 2017 by Johny Chen, Telesis Technologies, Inc.

The Customer Challenge

Manufacturers of bone screws, bone plates, artificial joints and other implantable devices face many challenges. Producing safe and flawless devices is by far the most important consideration because an implant is inserted into the human body where it often remains permanently.

In terms of regulation, manufacturers must comply with complex government product labeling requirements for reasons of safety, traceability and compliance, among others. In order to produce these medical devices with the highest quality and impeccable precision, there is a constant demand for exceptional laser marking systems and dedicated service partners. In this Industry Solution Guide, let Telesis demonstrate how we are the best choice in meeting these challenges.

The Telesis Solution – F Series Fiber Laser

Patient well-being and product safety are the top priorities of device manufacturers because implants like bone screws and artificial joints remain in the body for an extended period of time – often permanently.

Special care must be made to ensure that the implantable device is resistant to bacterial growth and maintains its corrosion resistant quality. When the material surface is damaged during the marking process, bacteria may accumulate, which can potentially cause infections and other serious problems.

The Telesis F Series line of high performance fiber lasers is capable of making delicate annealed marks without any superficial damage, safeguarding the integrity of the product. This series of low-maintenance yet highly dependable lasers produce consistent and precise results.

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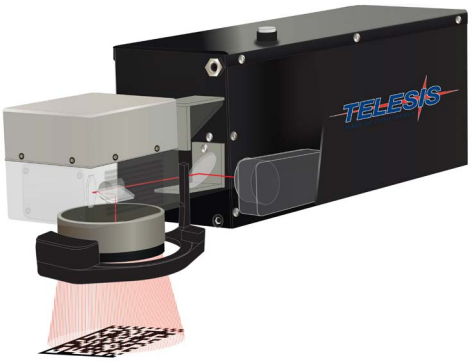
The Telesis Solution – In-Line Vision System

Because implantable devices like bone screws must be manufactured to extremely tight tolerances, repeatability of process and uniformity of final product become very important factors. With small surface areas for product identification, satisfying those factors becomes a challenge.

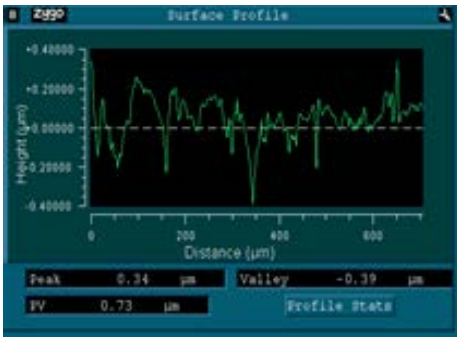
Fortunately, Telesis offers the In-Line Vision system which has an internal camera to combine marking, reading and validating of data matrix codes into an integrated system. The laser marking head's internal camera saves the customer both complexity and space. Combined with the easy to use Telesis Merlin® II LS software, the In-Line Vision laser system becomes a powerful tool that fulfills manufacturing requirements.



The Telesis Solution – Zygo 3D Optical Surface Profiler

Telesis relies on a variety of methods to inspect the quality of our sample marks - among them is the use of a Zygo 3D optical surface profiler. It is a validation tool that scans the marked area for any surface depth changes, thereby confirming whether any penetration occurred.

Even though customers follow their own validation specifications, our deployment of the surface profiler is an important first step towards qualifying Telesis laser systems.



The Telesis Solution – More Than Just Machines

For many years, Telesis has been a trusted partner in delivering laser solutions to world-class medical device manufacturers. All of our customers are supported by teams of engineers who are ready to offer application consultation, pattern design, training and installation services.

Telesis project engineers can also customize laser systems to unique production requirements. In addi-

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tion, our PLC experts offer important experience and knowhow in bringing connectivity to customer manufacturing processes. In today's competitive environment, we pride ourselves in providing timely response and service that customers truly value.

The Telesis Solution – Unique Device Identification (UDI) Regulation

This document is not intended as an exhaustive summary of UDI regulation, but it does offer a few items to note:

- The FDA describes UDI "as a unique numeric or alphanumeric code that consists of two parts: 1) a device identifier such a manufacturer and model name; 2) a production identifier like batch number and serial number."
- UDI is a system that includes a unique device identifier in human- and machine readable- form.
- UDI offers benefits on identification, traceability, reduction of errors, prevention of counterfeits, management of recalls, and more.
- Proposed UDI regulations between the FDA and the EU are very similar as they wish to bring uniformity and consistency to global manufacturers, users and other partners.
- The system will be phased in over several years.
- Telesis lasers markers can apply GS1 compliant standard and 2D barcodes.

GS1 Compliant 2D Code

Telesis offers a diverse lineup of marking systems to satisfy UDI marking requirements on a wide variety of materials. Customers can count on our years of experience to provide dependable and complete marking solutions.

Give us a call at 1-800-654-5696 or visit www.telesis.com.